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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tina Bruce

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EXAMINER

REICHLE, KARIN M

ART UNIT

PAPER NUMBER

3761

NOTIFICATION DATE

DELIVERY MODE

08/18/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/524,130	Applicant(s) BRUCE ET AL.	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008 and 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2008 is/are: a) ☒ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendments to the specification and abstract filed 5-9-08 still do not comply with 37 CFR 1.121. For example the abstract is not presented on a separate page. For another example, the amendments to page 4, lines 24-25 and page 6, lines 20-31 do not show all the changes made to the existing text to arrive at the proposed text. Therefore, such have not been entered. Accordingly the following action is based on the specification and abstract as originally filed, the proposed drawings and remarks filed 1-25-08 and the claims and remarks filed 5-9-08.

Specification

Drawings

2. The drawings were received on 1-25-08. These drawings are approved. However see the following paragraph.

3. The drawings are objected to because Figures 3 and 6 are inconsistent with the descriptions thereof on page 4, lines 24-25 and 29, i.e. a method is not shown and a nursing bra is not shown. See discussion in paragraph 1 supra. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

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where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

4. The abstract of the disclosure is objected to because the abstract, a copy of the PCT abstract, is acceptable for filing purposes only. A clean copy of such must be filed prior to allowance, if any. Also, legal terminology, i.e. “comprises” and “comprising”, should be avoided. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: 1) On page 2, lines 5-6, “patent No. 5,394,899” should be --Patent No. 5,394,889--. 2) On page 1, line 6, “membrane” should be --shield--. 3) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims should be commensurate in scope, see 608.01(d). Also see the following paragraph. 4) On page 5, line 21, “Silicone” should be --silicone--. 5) On page 6, line 13, “10,as” should be --10, as--. 6) On page 6, line 22, should “vice” be --versus--? 7) The description of Figures 3 and 6 on page 7, lines 16-17 and 25 is inconsistent with the Figures and/or the description on page 4, lines 24-25 and 29, see also discussion supra. 8) Claims 18 and 21-25 require a method consisting of certain steps. See also

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the discussion in section 3) supra and the following paragraphs. However, such method as claimed and the method as disclosed appear to be inconsistent, at the very least. For example, the method as claimed in claim 18 consists of the steps of placing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame laminated to an inner membrane against a nipple of a lactating human female; and depressing the nipple, wherein the inner membrane of the shield contacts the nipple. However, this is not the method as described, e.g., at page 2, line 30-page 3, line 1, page 3, lines 1-2, 4-6, 12-17, 21-24, 24-25, and 26-29, page 3, line 31-page 4, line 2 and page 7, lines 16-20 of the description. For another example, the method for controlling leakage in claim 22 only requires placing a specific shield within the cup of a bra, however this not the method as described, e.g., at page 2, line 30-page 3, line 1, page 3, lines 1-2, 4-6, 12-17, 21-24, 24-25, and 26-29, page 3, line 31-page 4, line 2 and page 7, lines 16-20 of the description, e.g. method includes wearing of the bra. A clear consistent description of the steps of a method which prevent let down should be set forth throughout the application.

Appropriate correction is required.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: clear antecedent basis for the invention as claimed in claims 18 and 21-25, at the very least, should be set forth. However note the discussion supra as well as in paragraph 9 infra.

Claim Objections

7. Claims 22-25 are objected to because of the following informalities: In claim 24, section (c), “the inside....an outside” should be --an inside of a cup of a bra--. In section (d), insert --and-- after “;”. In claim 22, where is a transitional phrase, e.g. “comprising”, i.e. where does the preamble end and claim body begin? Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 18 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The methodology of controlling/preventing breast milk leakage critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See the steps of which the method for preventing leakage of lactating fluid in female humans consists of in claims 18 and 21 and comprises in claims 22-25, i.e. placing and depressing a specific shield alone or placing a specific shield inside a bra at a minimum or placing a specific shield having an adhesive applied to it inside a bra and placing the bra on the female and maintaining, see *infra*, pressure at a minimum, then see page 1, lines 4-5, page 2, lines 4-5, page 2, line 30-page 3, line 1, page 3, lines 1-2, 4-6, 12-17, 21-24, 24-25, and 26-29, page 3, line 31-page 4, line 2 and page 7, lines 16-20 of the description of the instant disclosure, e.g. specifically placing and then depressing a specific shield of silicone rubber compounds of low durometer with regard to the nipple and then pressing the shield against the skin surrounding the nipple and keeping it in contact therewith without adhesives due to inherent tackiness of silicone rubber compounds of low durometer alone. See also discussion *supra* and *infra*

9. Claims 18 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 now sets forth a method for preventing breast milk leakage in female humans consisting of placing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame laminated to an inner membrane against a nipple of a lactating human female; and depressing the nipple, wherein the inner membrane of the shield contacts the nipple. New claim 22 recites a method for controlling breast milk leakage in human females by, i.e. “comprising” as best understood, see discussion supra in paragraph 7, placing a reusable, washable, thin, flexible, breathable, liquid impervious shield inside a cup of a bra, wherein the shield has an exterior frame laminated to an inner membrane, and an outer-facing side and wherein the cup includes an inside and an outside, and securing at least a perimeter of the outer-facing side of the shield to the inside of the cup. New claim 24 recites a method for controlling breast milk leakage in human females comprising the steps of (a) providing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame laminated to an inner membrane, wherein the exterior frame has an outer-facing side; (b) applying an adhesive to at least a perimeter of the shield on the outer-facing side; (c) placing the shield on the inside of a cup of a bra, wherein the cup includes an inside and an outside; (d) placing the bra on a lactating human female wherein the shield directly contacts each breast of the female; and (f) maintaining pressure sufficient to depress each nipple of the female. At the very most (see the discussion in paragraphs 5 -6 and 8 supra), these are not the steps, i.e. the

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method, for preventing/controlling breast milk leakage in human females. If Applicant maintains such claimed methodology, the portion of the originally filed application, e.g. page number, line number, which provides support for the entire scope of such in a single embodiment should be set forth.

10. Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 24, a positive antecedent basis for “maintaining pressure sufficient to depress each nipple”, section (f), should be set forth, i.e. where is applying pressure to depress each nipple initially claimed such that it is maintained in section (f)?

Claim Language Interpretation

11. Since no claim terminology has been explicitly defined in the application the terminology will be given its usual, i.e. dictionary, definition. “Membrane” is defined by the dictionary as “a thin sheet of material”. It is further noted that the terminology “thin” is considered relative absent claiming of specific dimensions thereof. “Laminated” is defined as “to make by uniting several layers” and “lamine” is thereby considered to be several united layers, i.e. united directly or indirectly. “Bra” is defined as “a woman’s undergarment to cover and support the breast”.

Claim Rejections - 35 USC § 102

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by Morrissey et al '930.

See the Claim Language Interpretation section supra, hereinafter also referred to as CLI, and '930 at, e.g., the Figures, and paragraphs 52, 46, 49, 3, 12, 39, 40-42, 44-45, 50 and 54, i.e. '930 teaches a method for controlling breast milk leakage in human females, by, i.e. "comprising" as best understood, see discussion supra in paragraph 7, placing a reusable, "thin", "flexible", breathable, i.e. permits air circulation, liquid impervious, i.e. of molded plastic or rubber and/or paragraph 39, i.e. "eliminates fluid release", shield 1 inside a cup of a bra 11, wherein the shield has an exterior frame 2a "laminated" to an inner membrane, i.e. 9 and/or the attachment devices, see paragraph 42, and an outer-facing side and wherein the cup includes an inside and an outside, and securing at least a perimeter of the outer-facing side of the shield to the inside of the cup, see, e.g., Figure 1 and paragraph 52. The claim further requires the shield be "washable", i.e. a property, function or capability of the shield. However, see discussion supra, includes all the claimed structure and, e.g., paragraphs 54, 52, and 46, i.e. reuseable, can be integrated into the cup of a bra, of materials capable of washing. Therefore, it is the Examiner's position that there is sufficient factual evidence for one to conclude that at the very

least such similarly structured shield of '930 also inherently includes the same properties, functions or capabilities, i.e. washable, see MPEP 2112.01 and 2112.02.

Claim Rejections - 35 USC § 103

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrissey '903 in view of Furano et al '195.

Claim 23 requires a shield made of silicone rubber while '903 only teaches such being a molded flexible rubber, see paragraph 46. However, see, e.g., '195 at the Figures, col. 1, lines 20-23, 26-28, and 52-55 and col. 2, lines 7-13, i.e. '195 teaches a re-useable nipple cover, i.e. shield, of molded flexible rubber which comprises a silicone rubber compound. To make the molded flexible rubber of the shield of '903 of silicone rubber instead, if not already, as taught by '195 would be obvious to one of ordinary skill in the art in view of either *In re Siebentritt*, 54 CCPA 1083, i.e. two equivalents are interchangeable for the desired function, express suggestion of desirability not needed to render such substitution obvious, or that such would provide a comfortable reuseable molded rubber shield and the desire by '903 to provide such.

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrissey et al '903 in view of Cole '267.

See discussion of claim 21 *supra*, i.e. '903 teaches or necessarily and inevitably teaches a method for controlling breast milk leakage in human females comprising the steps of providing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame

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laminated to an inner membrane, wherein the exterior frame has an outer-facing side; placing the shield on the inside of a cup of a bra, wherein the cup includes an inside and an outside; placing the bra on a lactating human female wherein the shield directly contacts each breast of the female; and (f) maintaining pressure sufficient to depress each nipple of the female. Note again the cited portions of '903 as well as claims 16 and 20. Claim 25 further requires the step of applying an adhesive to at least a perimeter of the shield on the outer-facing side. While '903 teaches integrating the shield with the cup of a bra by, for example, sewing such into the cup, see paragraph 52, as well as showing the perimeter of the outer facing side of the shield attached to the cup it does not teach such via an adhesive. However, see '267 at, e.g., col. 2, lines 65-66, col. 4, lines 3-4 and 45-47 and the Figures, i.e. adhesive can be used to integrate a compressive nipple cover into a bra cup rather than sewing. To make the sewn integration of the shield of '903 adhesive integration instead would be obvious to one of ordinary skill in the art in view of the teachings of interchangeability as taught by '267.

17. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrissey et al '903 in view of Cole '267 as applied to claim 24 above, and further in view of Furano '195.

See discussion of claim 23 supra.

Allowable Subject Matter

18. The prior art references, either alone or in combination, do not teach a method of leakage prevention which consists only of the steps claimed in claims 18 and 21. See discussion of such claims in paragraphs 5-6 and 8-9 supra though.

Response to Arguments

19. Applicant's remarks have been carefully considered but are either deemed moot in that the issue discussed has not been repeated or deemed not persuasive for the reasons set forth supra.

Conclusion

208. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant's attention is also directed to '639 at col. 7, lines 54-59 and redirected to col. 4, lines 28-37 of '629 and col. 4, lines 62-65 of '693 already of record.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the cancellation of claims 1-17 and 19-20, the amendments to claim 18 and the addition of claims 21-25.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karin M. Reichle/
Primary Examiner, Art Unit 3761

August 9, 2008